different. In particular: (1) compounds 1-4 utilized a one step process while compounds 5 and 6 utilized a two step process; (2) compounds 1 and 5 utilized an acetonitrile mobile phase, compound 2 utilized an ethanol mobile phase, compound 3 utilized a methanol mobile phase, compound 4 utilized a methanol/ethanol (10:90, v/v) mobile phase, and compound 6 utilized an acetonitrile-0.1% acetic acid mobile phase.

The position taken by the Office to support this rejection is inconsistent with established case law and constitutes, at best, an "obvious to try" rejection. In *In re O'Farrell*, 7 USPQ2d 1673 (Fed. Cir. 1990), the Court of Appeals for the Federal Circuit discussed the impropriety of "obvious to try" rejections, stating:

> The admonition that "obvious to try" is not the standard under § 103 has been directed mainly at two kinds of error. In some cases, what would have been obvious to try would have been to vary all possible parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art either gave no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. (*Id.* at 1681, citations omitted)

In the present case, because Miller et al. do not describe the structures of any of the compounds they reportedly separated, it is impossible for one of ordinary skill in the art to predict what separation conditions employed by Miller and coworkers might actually be useful for resolving a compound of a desired structure and having associated physicochemical properties. It is even more significant that different conditions were needed to resolve the six unknown compounds according to the Miller et al. disclosure.

The instant record is therefore clear that Miller et al. fail to provide sufficient direction as to which of many possible separation conditions might be successful for a particular compound or class of compounds.

It is further noted that all of the separations of Miller et al. utilized a polar organic phase. In contrast, the invention as presently claimed requires a mobile phase comprising a hydrocarbon solvent adjusted in polarity with a miscible polar organic solvent. At page 212, left column, Miller et al. specifically contrast their methods with methods employing hydrocarbon based mobile phases. In this context, the teachings of Miller et al. teach away from the instantly-claimed invention.

Applicants further submit that improper, hindsight reconstruction has been employed by the Office to support the instant rejection. In the Office Action dated April 11, 2005, the examiner stated:

> Applicant argues that, according to the Office, the process of Miller et al., must meet a standard applicable to any and all racemates (sic) compounds. This may not be true

> for any and all racemates but it is true for applicant's racemates *as confirmed by applicant's invention*. Otherwise, the process of Miller et al., would not have separated applicant's racemates. The fact that the process of Miller et al., is applicable for separating applicant's racemates implies applicant's compound is analogous to that of Miller et al. Applicant should note that the use of analogous starting material in a well-known process is prima facie obvious. *In re Durden*, 226 USPQ 359 (1985) [Office Action, page 5, *emphasis added*]

This statement represents a conclusion that Applicant's compound is analogous to the (uncharacterized) compounds of Miller et al., on which basis Applicant's invention is allegedly obvious under 35 USC §103. This reasoning is factually based primarily on Applicants' own experimental results, reflecting impermissible hindsight reconstruction. As noted by the Court of Appeals for the Federal Circuit in Life Technologies, Inc. v. Clontech Laboratories, Inc., 56 USPQ2d 1186 (Fed. Cir. 2000):

> That the inventors were ultimately successful is irrelevant to whether one of ordinary skill in the art, at the time the invention was made, would have reasonably expected success....The court's finding to the contrary represents impermissible use of hindsight-using the inventor's success as evidence that the success would have been expected.

The conclusion that Applicant's compound is analogous to the compounds of Miller et al. is unsupported by the record, because Miller and coworkers fail to describe the structure of any of the reportedly resolved compounds. The further extrapolated conclusion that Applicants' invention is obvious under 35 USC § 103 based on Applicant's own experimental results is clearly improper in view of the foregoing authority.

Accordingly, Applicants respectfully submit that the rejection of Claims 53-62 under 35 USC § 103(a) as allegedly unpatentable over Miller et al. is overcome.

CONCLUSION

In view of the foregoing, Applicants believe that all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at (425) 455-5575.

Respectfully submitted,

Dated November 14, 2005

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